

Cost reporting year ending	Rate of return on equity capital (percent)
Dec. 31, 1970	4.538
Dec. 31, 1971	8.969
Dec. 31, 1972	8.891
Dec. 31, 1973	9.969
Total	32.367

(The \$100,000 paid in excess of the fair market value of the assets acquired is included in equity capital until the sum of the allowable rate of return on equity capital equals 100 percent. Of course, no portion of the \$100,000 may be amortized as an allowable cost or is otherwise allowable for any program reimbursement purposes other than for determining the provider's equity capital.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 52 FR 32921, Sept. 1, 1987; 53 FR 12017, Apr. 12, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 26960, May 25, 1994]

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services

§ 413.170 Payments for covered outpatient maintenance dialysis treatments.

(a) *Basis and purpose.* This section implements section 1881 (b)(2) and (b)(7) of the Act by—

(1) Setting forth the principles and authorities under which HCFA is authorized to establish a prospective reimbursement system for outpatient maintenance dialysis furnished in or under the supervision of an ESRD facility approved under subpart of part 405 of this chapter (referred to as “facility” in this section). For purposes of this section and § 413.174, outpatient maintenance dialysis means outpatient dialysis, home dialysis and self-dialysis, and home dialysis training as defined in § 405.2102 (f)(2)(ii), (f)(2)(iii), and (f)(3) of this chapter, and includes all items and services specified in §§ 410.50 and 410.52 of this chapter.

(2) Providing for procedures and criteria under which a facility may receive an exception to the prospective payment rates established under this section; and

(3) Establishing procedures and criteria for a facility to appeal its reim-

bursement under the prospective reimbursement system.

(b) *Principles of prospective reimbursement.* (1) Under prospective reimbursement, payments for outpatient maintenance dialysis are based on rates set prospectively by HCFA.

(2) All approved ESRD facilities must accept the prospective payment rates established by HCFA as payment in full for covered outpatient maintenance dialysis.

(3) HCFA will publish the methodology used to establish rates and changes in payment rates in the FEDERAL REGISTER, as provided in paragraph (i)(2) of this section.

(c) *Prospective rates for hospital-based and independent ESRD facilities.* (1) In accordance with section 1881(b)(7) of the Act, HCFA will establish prospective rates by a methodology that—

(i) Differentiates between hospital-based facilities and independent ESRD facilities;

(ii) Effectively encourages efficient delivery of dialysis services; and

(iii) Provides incentives for increasing the use of home dialysis.

(2) For purposes of rate-setting and reimbursement under this section, HCFA will consider any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph is an initial determination under § 405.1502 of this chapter.

(3) For purposes of rate-setting and reimbursement under this section, HCFA will determine that a facility is hospital-based if the—

(i) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. All authority in management flows from this governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(ii) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(iii) Facility personnel policies and practices conform to those of the hospital;

(iv) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(v) Facility and hospital are financially integrated, as evidenced by the cost report, which must reflect allocation of overhead to the facility through the required step-down methodology.

(4) In determining whether a facility is hospital-based, HCFA will not consider—

(i) An agreement between a facility and a hospital concerning patient referral;

(ii) A shared service arrangement between a facility and a hospital; or

(iii) The physical location of a facility on the premises of a hospital.

(5) If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in §414.313(c)), the prospective rate (as described in paragraph (c)(1) of this section) paid to that facility will be increased by an add-on amount as described in §414.313 of this chapter.

(6) *Epoetin (EPO)*. (i) When EPO is furnished to an ESRD patient by a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies, payment is based on the amount specified in paragraph (c)(6)(iii) of this section.

(ii) The payment is made only on an assignment basis, that is, directly to the facility or supplier, which must accept, as payment in full, the amount that HCFA determines.

(iii) HCFA determines the payment amount in accordance with the following rules:

(A) The amount is prospectively determined.

(B) HCFA publishes annually a FEDERAL REGISTER notice, indicating whether an update in the EPO payment amount is appropriate and requesting public comment.

(C) Any increase in this amount does not exceed the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the

second quarter of the second preceding year.

(D) HCFA sets a single amount to be paid nationwide to hospital-based and independent dialysis facilities and to suppliers of home dialysis equipment and supplies, regardless of the location of the facility, supplier, or patient.

(E) The Medicare payment is subject to the Part B deductible and coinsurance.

(7) In addition to the prospective payment described in this section, HCFA makes an additional payment for certain drugs furnished to ESRD patients by a Medicare-approved ESRD facility. HCFA makes this payment directly to the ESRD facility. The facility must accept the allowance determined by HCFA as payment in full. Payment for these drugs is made to the following facilities according to the methodology described:

(i) *Hospital-based*. HCFA makes payment in accordance with the cost-reimbursement rules set forth in this part.

(ii) *Independent*. HCFA makes payment in accordance with the methodology set forth in §405.517 of this chapter for paying for drugs that are not paid on a cost or prospective payment basis.

(d) *Amount of payments*. (1) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the treatment, the intermediary will pay the facility 80 percent of its prospective payment rate.

(2) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the treatment, the intermediary will subtract the amount applicable to the deductible from the facility's prospective rate, and will pay the facility 80 percent of the remainder, if any.

(e) *Bad debts*. (1) HCFA will reimburse each facility its allowable Medicare bad debts, up to the facility's costs as determined under Medicare principles, in a single lump sum at the end of the facility's cost reporting period.

(2) A facility must attempt to collect deductible and coinsurance amounts owed by beneficiaries before requesting reimbursement from HCFA for uncollectible amounts. Section 413.80 specifies the efforts facilities must make.

(3) A facility must request reimbursement for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list of all specific noncollections related to covered services.

(f) *Procedures for requesting exceptions to payment rates.* (1) All payments for outpatient maintenance dialysis furnished at or through facilities will be made on the basis of prospective payment rates, without exemption.

(2) If a facility projects on the basis of prior year cost and utilization trends that it will have an allowable cost per treatment higher than its prospective rate set under this section, and if these excess costs are attributable to factors related to one or more of the criteria in paragraph (g) of this section, the facility may request HCFA to approve an exception to that rate and set a higher prospective payment rate.

(3) This higher payment rate will be subject to the rules governing the amount of payment in paragraph (d) of this section.

(4) A facility must request an exception to its payment rate within 180 days after—

(i) It is notified of its prospective payment rate; or

(ii) An extraordinary event with substantial cost effects, as described in paragraph (g)(4) of this section.

(5) The facility is responsible for demonstrating to HCFA's satisfaction that the requirements of this section, including the criteria in paragraph (g) of this section, are met in full. That is, the burden of proof is on the facility to show that one or more of the criteria are met, and that the excessive costs are justifiable under the reasonable cost principles set forth in this part. The burden of proof is not on HCFA to show that the criteria are not met, and that the facility's costs are not allowable.

(6) If requesting an exception to its payment rate, a facility must submit to HCFA its most recently completed cost report as required under § 413.174, and whatever statistics, data, and budgetary projections are determined by HCFA to be needed to determine if the exception is approvable. HCFA may audit any cost report or other informa-

tion submitted. The materials submitted to HCFA must—

(i) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(ii) Show that all of the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(iii) Show that the elements of excessive cost are specifically attributable to one or more conditions specified by the criteria set forth in paragraph (g) of this section; and

(iv) Specify the amount of additional reimbursement per treatment the facility believes is required in order to recover its justifiable excess costs.

(7) HCFA will accept an exception request on the date that HCFA concludes that it has received all materials necessary to determine if the exception is approvable.

(8) In determining the facility's payment rate under the exception process, HCFA will exclude all costs that are not allowable under the reasonable cost principles set forth in this part.

(9) Except for exceptions approved under paragraph (g)(4) of this section, a prospective exception payment rate approved by HCFA will apply for the period from the date the exception request was accepted until the earlier of the—

(i) Date the circumstances justifying the exception rate no longer exist; or

(ii) End of the 12-month period during which the announced rate was to apply.

(10) A prospective exception payment rate approved by HCFA under paragraph (g)(4) of this section will apply from the date of the extraordinary event until the end of the 12-month period during which the announced rate was to apply, unless HCFA determines that another date is more appropriate. If HCFA does not extend the exception period, and the facility believes that it continues to require an exception to its rate, the facility must reapply in accordance with paragraph (f) of this section.

(g) *Criteria for approval of exception requests.* HCFA may approve exceptions

to an ESRD facility's prospective payment rate if the facility demonstrates with convincing objective evidence that its total per treatment costs are reasonable and allowable under § 413.174, and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(1) *Atypical service intensity (patient mix)*. A substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients. The facility is able to demonstrate clearly that these services, procedures or supplies and its per treatment costs are prudent and reasonable when compared to those of facilities with a similar patient mix. Examples that may qualify under this criterion are more intense dialysis services that are medically necessary for patients such as—

(i) Patients who have been referred from other facilities on a temporary basis for more intense care during a period of medical instability, and who return to the original facility after stabilization;

(ii) Pediatric patients, who require a significantly higher staff-to-patient ratio than typical adult patients; or

(iii) Patients with medical conditions that are not commonly treated by ESRD facilities, and that complicate the dialysis procedure.

(2) *Isolated essential facility*. The facility is the only supplier of dialysis in its geographical area, its patients cannot obtain dialysis services elsewhere without substantial additional hardship, and its excess costs are justifiable. HCFA will consider local permanent residential population density, typical local commuting distances for medical services, volume of treatments, and dialysis facility usage by area residents other than the applying facility's patients, in determining whether an exception requested on this basis is approvable.

(3) [Reserved]

(4) *Extraordinary circumstances*. The facility incurs excess costs beyond its control due to a fire, earthquake, flood, or other natural disaster. HCFA will

not recognize such costs in cases when a facility chose not to maintain adequate insurance protection against such losses (through the purchase of insurance, the maintenance of a self-insurance program, or other equivalent alternative) or chose not to file a claim for losses covered by insurance, or not to utilize its self-insurance program.

(5) *Self-dialysis training costs*. The facility incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for such training sessions.

(6) *Frequency of dialysis*. The facility has a substantial proportion of patients who dialyze less frequently than three times per week. Per treatment payment rates granted under this exception will be no more than the amount that results in weekly reimbursement per patient equal to three times the facility's prospective composite rate, exclusive of any exception amounts.

(h) *Appeals*. (1) *Appeals under section 1878 of the Act*. A facility that disputes the amount of its allowable Medicare bad debts reimbursed by HCFA under paragraph (e) of this section may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R of part 405 of this chapter.

(2) *Other appeals*. A facility that has requested higher payment per treatment in accordance with paragraph (f) of this section may request a review from the intermediary or the PRRB if HCFA has denied the request in whole or in part. In such a case, the procedure in subpart R of part 405 of this chapter will be followed to the extent that it is applicable. The PRRB, subject to review by the Administrator under § 405.1875 of this chapter, will have the authority to determine whether the HCFA action under review conformed to the provisions of paragraph (f).

(3) *Procedure*. (i) The facility must request a review within 180 days of the date of the decision on which review is sought.

(ii) The facility may not submit to the intermediary or the PRRB any additional information or cost data that were not submitted to HCFA at the

time the facility requested an exception to its prospective payment rate.

(4) *Determining amount in controversy.* For purposes of determining PRRB jurisdiction under subpart R of part 405 of this chapter for the appeals described in paragraph (h)(2) of this section—

(i) The amount in controversy per treatment will be determined by subtracting the amount of program payment from the amount the facility requested under paragraph (f) of this section; and

(ii) The total amount in controversy will be calculated by multiplying the amount per treatment by the projected estimated number of treatments for the exception request period (as specified in paragraphs (f) (7) and (8) of this section).

(i) *Notification of changes in rate-setting methodologies and payment rates.* (1) HCFA or the facility's intermediary will notify each facility annually of its payment rate. This notice will include changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(2) Changes in payment rates resulting from incorporation of updated cost data, or general revisions of geographic labor cost adjustment factors, will be announced by notice published in the FEDERAL REGISTER without opportunity for prior public comment. Other revisions of the rate-setting methodology will be published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[51 FR 34793, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986, as amended at 54 FR 40319, Sept. 29, 1989; 55 FR 23441, June 8, 1990; 56 FR 43710, Sept. 4, 1991; 56 FR 59624, Nov. 25, 1991; 59 FR 1285, Jan. 10, 1994]

§ 413.174 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and scope.* This section implements section 1881(b)(2)(B)(i) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities approved under subpart U of part 405 of this chapter. The records and reports will enable HCFA to determine the costs incurred in fur-

nishing outpatient maintenance dialysis as defined in § 413.170(a)(1).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate HCFA-approved cost report in accordance with §§ 413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with § 413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis services, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

(i) Are not related to patient care for outpatient maintenance dialysis;

(ii) Are for services or items specifically not reimbursable under the program;

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

(iv) Are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

(i) Section 413.157, Return on equity capital of proprietary providers;

(ii) Section 413.178, Reimbursement of OPAs and histocompatibility laboratories;